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Indian Standard

SPECIFICATION FOR NEEDLE HOLDER, EYE, CASTROVIEJO'S PATTERN

- 1. Scope Covers dimensional and other requirements for Castroviejo's pattern needle holder with or without catch used in eye surgery.
- 2. Shape and Dimensions As shown in Fig. 1.
- 3. Material
- **3.1** The needle holder shall be of stainless steel conforming to Designation 30Cr13 of IS: 6603-1972 'Specification for stainless steel bars and flats'.
- 3.2 Screw and pins shall be made of the same material as used for the needle holder.
- 4. Workmanship and Finish
- 4.1 The surface of the needle holder shall be free from seams, burrs, pits, flaws and other defects.
- 4.2 The edges shall be even and rounded.
- 4.3 The component halves shall open and close fully and freely without any undue side play at the joint.
- 4.4 The jaws shall have matt finish. On closure, the jaws shall meet fully and accurately.
- **4.5** The catch and latch arrangement shall work effectively and shall lock the needle holder in one pressing and unlock in the other pressing.
- 4.6 The needle holder shall be symmetrical and well-balanced.
- 4.7 The needle holder shall be polished bright, passivated and demagnetized.
- 5. Heat Treatment The needle holder shall be hardened and tempered to give a hardness of 430 to 490 HV.
- 6. Tests
- **6.1** Performance A suture needle of 5 mm length, half-circle type shall be gripped between the jaws and the needle shall be made to pierce a piece of soft leather 0.5 mm thick. The needle held by the jaws shall not slip. The needle holder shall also be able to grip 8.0 thread without slippage.
- 6.2 Flexibility
- **6.2.1** A force of moderate degree by the fingers shall be applied to each shank attempting to bend the shank on the width. This shall be repeated at several points along the shanks. The test shall then be repeated in a plane at right angles to the first. On completion of the test, the shank shall not have acquired permanent set.
- 6.2.2 The terminal 5 mm of the jaws shall be made to bite on a piece of firm rubber 2 mm thick and the needle holder closed by manual compression force. This test shall be repeated six times. On completion of this test, the jaws shall continue to meet accurately.
- 6.3 Corrosion Resistance The instrument shall satisfy the boiling and autoclaving test as specified in IS: 7531-1975 'Method for boiling and autoclaving test for corrosion resistance of stainless steel surgical instruments'.
- 7. Marking Each needle holder shall be legibly and indelibly marked with the manufacturer's name, or initials or recognized trade-mark.
- 7.1 ISI Certification Marking Details available with the Indian Standards Institution.
- 8. Packing As agreed to between the purchaser and the supplier.

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@ August 1976, ISI



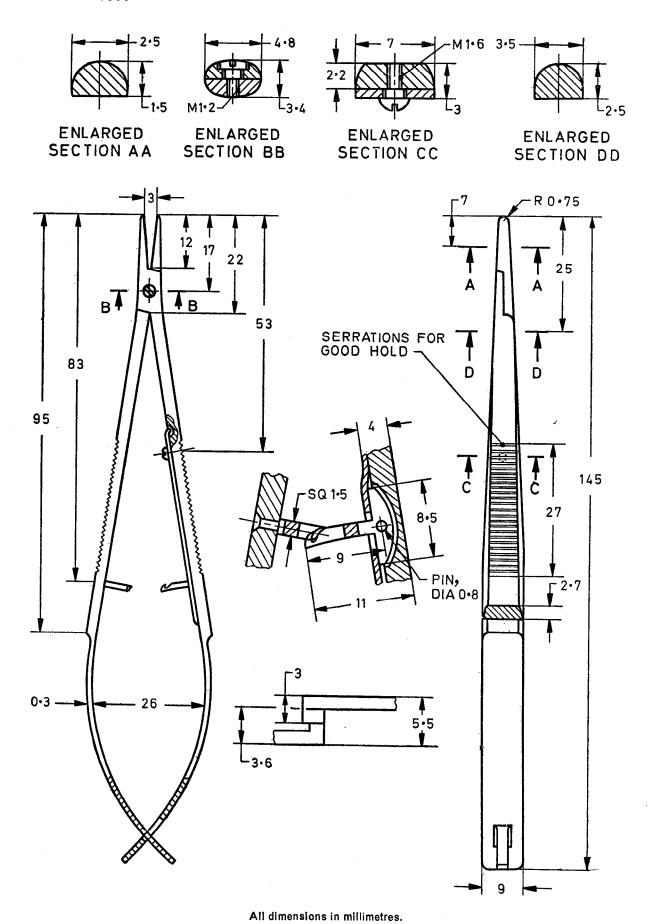


FIG. 1 NEEDLE HOLDER, EYE, CASTROVIEJO'S PATTERN